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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,628	01/08/2002	David M. Duffy	14682P001	6517

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EXAMINER	
TRUONG, LINH T	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,628	DUFFY, DAVID M.	
	Examiner	Art Unit	
	Linh Truong	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *7,9,10,12-34,41-52 and 60-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,11,35-40 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 27-59 are drawn to a method of treating a skin defect, classified in class 604, subclass 290.

II. Claims 12-26 and 60-70 drawn to an apparatus for treating a skin defect, classified in class 604, subclass 318.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to aspirate fluids from a wound.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

NOTE: APPLICANT MUST ELECT EITHER INVENTION I OR II. IF APPLICANT ELECT INVENTION I THAN APPLICANT MUST ALSO ELECT ONE OF THE FOLLOWING FOUR PATENTABLY DISTINCT SPECIES:

1. Species 1 is drawn to a method of treating a depressed skin defect by injecting a bioactive material (claims 7, 27-34).

2. Species 2 is drawn to a method of treating a depressed skin defect by performing subcision (claims 8, 35-40).

3. Species 3 is drawn to a method of treating a depressed skin defect by laser therapy (claims 9, 41-46).

4. Species 4 is drawn to a method of treating a depressed skin defect by chemical peeling (claims 10, 47-52)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 11, and 53-59 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Bereznak on 23 June 2004 a provisional election was made without traverse to prosecute the invention of I, species 2 claims 1-6, 8, 35-40, and 53-59. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7, 9-10, 12-34, 41-52, and 60-70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 11, 53-54, 56, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Khouri '5,701,917 (IDS).

With respect to claims 1-2, 4, 11, 53-54, 56, and 59, Khouri teaches a method for treating skin defects (e.g. skin dimples and open sores) comprising: a) applying a vacuum pressure to the skin defect, b) regulating the vacuum pressure within a prescribed range of pressures between 25-35 mmHg, c) releasing the vacuum pressure after a time interval (col. 4, lines 20-46), and repeating the aforementioned steps one or more times (col. 5, lines 58-61) without harming the surrounding tissue.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-5, 11, 32, 53-54, 56, and 59 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mallett et al. (Mallett) '6,592,595.

With respect to claims 1-2, 4-5, 11, 32, 53-54, 56, and 59, Mallet teaches a method for treating skin defects (e.g. cellulite and scars) comprising: a) applying a vacuum pressure to the skin defect, b) obviously regulating the vacuum pressure within a prescribed range of pressures because the pressures can be controlled and/or selected (it is also known in the art what range of pressures is safe and effective for skin treatments) (col. 6, lines 1-2 and 28-29)

for safety and treatment purposes, and obviously releasing the vacuum pressure after a time interval (col. 4, lines 20-46), and repeating the aforementioned steps one or more times (col. 2, lines 4 –5) without harming the surrounding tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallett et al. (Mallett) '6,592,595.

With respect to claims 3 and 55, Mallet discloses the claimed method except for a vacuum pressure range of 10 inches Hg-80 inches Hg. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a vacuum pressure range of 10 inches Hg-80 inches Hg, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105USPQ 233.

For claim 6, Mallett teaches the treatment of cellulite but does not expressly disclose treating wrinkles. But dermabrasion and endermologie are treatments used to smooth the skin by getting rid of skin defects and it is obvious to one with ordinary skill in the art that a wrinkle is a skin defect.

Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to use the endermologie treatment of Mallett to treat skin wrinkles.

Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallett et al. (Mallett) '6,592,595 in view of Applicant's own admission.

For claims 57-58, Mallet does not teach injecting the scar with the skin-weakening medicament, cortisone. As admitted by Applicant, it is common to inject cortisone into scars to change their structure [0033]. Therefore, it is obvious to one with ordinary skill in the art at the time the method was invented to provide the method of mallet with the additional step of injecting cortisone for treating scars more effectively.

Claims 8 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallett et al. (Mallett) '6,592,595 in view of Dr. Hexsel and Dr. Mazzuco ("Subcision: a treatment for cellulite. *International Journal of Dermatology* **39** (7), 539-544) and in further view of Applicant's prior art ("Subcutaneaous Incisionless (Subcision) Surgery for the Correction of Depressed Scars and Wrinkles" by Dr. David Orentreich and Dr. Norman Orentreich) (IDS).

For claims 8, 35, 37-38, and 40, Mallett teaches a method for treating skin defects (e.g. cellulite and scars) comprising: a) applying a vacuum pressure to the skin defect, b) obviously regulating the vacuum pressure within a prescribed

range of pressures because the pressures can be controlled and/or selected (it is also known in the art what range of pressures is safe and effective for skin treatments) (col. 6, lines 1-2 and 28-29) for safety and treatment purposes, and obviously releasing the vacuum pressure after a time interval (col. 4, lines 20-46), and repeating the aforementioned steps one or more times (col. 2, lines 4 –5) without harming the surrounding tissue. Mallet, however, does not teach the additional step of subcision. Subcision is well known, as taught by Drs. Orentreich, in the art for "...raising the defected skin to the level of the surrounding skin..." (see article) (applying vacuum pressure also has the same effect) and subcision is also well known in the treatment of cellulite, as disclosed by Dr. Hexsel and Dr. Mazzuco. Since scars, wrinkles, and cellulite are all skin defects, it is obvious to one with ordinary skill in the art to provide the skin treatment method of Mallett with the subcision step disclosed by Dr. Hexsel and Dr. Mazzuco and Drs. Orentreich in order to provide a complete skin defect treatment program.

With respect to claim 36, Mallet, Dr. Hexsel and Dr. Mazzuco, and Drs. Orentreich disclose the claimed invention except for a vacuum pressure range of 10 inches Hg-80 inches Hg. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a vacuum pressure range of 10 inches Hg-80 inches Hg, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105USPQ 233.

For claim 39, Mallett teaches the treatment of cellulite but does not expressly disclose treating wrinkles. But dermabrasion and endermologie are treatments used to smooth the skin by getting rid of skin defects and it is obvious that a wrinkle is a skin defect, as disclosed by Drs. Orentreich. Therefore, it is obvious to one with ordinary skill in the art at the time the combined treatments of Mallett, Dr. Hexsel and Dr. Mazzuco, and Drs. Orenreich can also be used to treat skin wrinkles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974. The examiner can normally be reached on Mondays to Fridays from 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

*** L.T.

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